

Appl. No 10/561,162

Reply to Office Action of December 31, 2008

is is chosen from the group consisting of: atorvastatin (Lipitor®), cerivastatin (Baycol®), fluvastatin (Lescol®), lovastatin (Mevacor®, Altocor®), pravastatin (Pravachol®), simvastatin (Zocor®), epistatin, eptastatin, mevinolin, and synvinolin.

23. (Withdrawn) A method as defined in claim 22, wherein said statin drug is simvastatin (Zocor®).

24. (Withdrawn) A method as defined in claim 22, wherein said statin drug is administered in an amount of about 0.1-2 mg/day.

25. (Withdrawn) A method as defined in claim 24, wherein said subject is a mammal.

26. (Withdrawn) A method as defined in claim 25, wherein said mammal is human.

REMARKS/ARGUMENTS

Claims 1-26 remain in this application. Claims 12 and 14 were previously presented. Claims 9 and 11 are currently amended. Claims 1-8 and 15-26 remain withdrawn. Claims 10 and 13 remain canceled.

Informalities.

The Examiner has objected to claim 3 for depending on a withdrawn claim and being identified as "original". Claim 3 is now properly identified as withdrawn and the Applicant respectfully submits that claim 3 is now in compliance with Patent Act and

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Rules.

The Examiner has rejected claim 11 for depending on a cancelled claim. Claim 11 now depends on claim 9, which is still pending, and the Applicant respectfully submits that claim 11 is now in compliance with Patent Act and Rules.

Claim rejections under 35 USC 102 and 35 USC 103.

The Examiner has rejected claims 9, 11 and 14 under 35 USC 102 as being anticipated by West et al. (2002, J. Hypertension, 20:2513-2517). The Examiner states that the reference teaches administering a statin to a patient with atrial fibrillation. The Examiner also combines West with US Patent 6,376,242, hereinafter Hanson, and US Patent 6,235,311, hereinafter Ullah to reject claims 9, 11-12 and 14 under 35 USC 103. The Examiner states that Hanson teaches administering a statin to a human suffering from atrial fibrillation and that Ullah teaches administering a statin to reduce the risk of cardiovascular event, including coronary artery disease.

Amended claim 9 reads as follows:

"A method of reducing the incidence of a first occurrence of atrial fibrillation (AF) by substrate modification comprising the step of administering to a mammal in need thereof an amount of a statin drug therapeutically effective for reducing the incidence of a first occurrence of atrial fibrillation in the mammal." (Emphasis added)

Amended claim 9 is directed to the prevention of a first occurrence of atrial fibrillation. The Applicant respectfully submits that there is absolutely no indication in West or Hanson that administering a statin can **prevent a first occurrence** atrial fibrillation. In fact, as stated by the Examiner, the patients referred to in these two documents already suffered from atrial fibrillation when the statin was administered. Therefore, if a statin is administered to a patient that already has atrial fibrillation, as

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stated by the Examiner, a **first occurrence of atrial fibrillation was not prevented**, as claimed in claim 9, which is in total contradiction with the claimed invention.

Furthermore, while Ullah discusses the prevention of coronary heart disease, **atrial fibrillation is a problem of the heart muscle in which the atrium contracts erratically and, the applicant respectfully submits, is not related to coronary heart disease, such as those discussed in Ullah**. More specifically, the Examiner understands that atrial fibrillation results in cardiovascular events, such as stroke and heart attack. The Applicant respectfully disagrees with the Examiner's understanding of the present invention and its relationship with Ullah. Indeed, cardiovascular events, such as stroke and heart attack, are related to coronary diseases caused by partial or total obstruction of a blood vessel. They typically result in death of heart tissue. **They are not caused by atrial fibrillation and atrial fibrillation is not a coronary heart disease and has no relationship to such diseases**. The Applicant also respectfully submits that a reader skilled in the art would have understood that the cardiovascular events referred to by Ullah are these coronary diseases, which have no relationship with and are not caused by atrial fibrillation. Accordingly, the Applicant respectfully submits that Ullah is not applicable to the present claim 9 as it relates to totally different diseases, and that Ullah nowhere discloses that a statin can prevent a first incidence of atrial fibrillation, as claimed in claim 9.

Finally, the Applicant respectfully submits that it would not be obvious that a substance administered to a patient after atrial fibrillation have occurred, as mentioned in West and Hanson, could have preventive effects, as claimed in claim 9. Indeed, heart tissue undergoes extensive remodelling and physiological changes after an episode of atrial fibrillation. **Since pre-atrial fibrillation heart tissue differs physiologically from post-atrial fibrillation heart tissue, the Applicant respectfully submits that the fact that statins can reduce a first occurrence of atrial fibrillation in subjects is not obvious in view of the use of statins in**

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patients already suffering from atrial fibrillation. This is a specific example of the well-known fact in medicine and biological science that a substance used to treat a condition is not necessarily useful in the prevention of this condition due to the complexity of the physiology of illness.

Accordingly, the applicant respectfully submits that the above-emphasized limitation of claim 9 is neither taught nor suggested by any of the references cited by the Examiner.

Claims 11-12 and 14 depend directly or indirectly on claim 9. As such, they include all the limitations of this base claim, including the above-discussed limitations. Accordingly, the Applicant respectfully submits that claims 11-12 and 14 are neither taught nor suggested by West, Hanson and Ullah, either taken alone or in combination.

Respectfully submitted,



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